

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Robert M. Townsend et al.

Examiner:

Phillip Gambel, Ph.D.

Serial No.:

09/877,987

Group Art Unit:

1645

Filed:

June 8, 2001

Docket:

D0009NP; 30436.53USU1

Title:

METHODS FOR REGULATING A CELL-MEDIATED IMMUNE RESPONSE BY BLOCKING LYMPHOCYTIC SIGNALS AND BY BLOCKING LFA-1-MEDIATED

ADHESION

CERTIFICATE UNDER 37 CFR 1.8

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By: Tracy Pruick

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Assistant Commissioner for Patents Washington, D.C. 20231

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Sir:

We are transmitting herewith the attached:

- Transmittal Sheet in duplicate containing Certificate under 37 C.F.R. 1.8
- Supplemental Information Disclosure Statement (37 C.F.R. §1.97(b))
- Form 1449 (Information Disclosure Statement)
- Exhibits 53-87
- Return postcard

Please charge any and/or additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

MANDEL & ADRIANO

55 South Lake Avenue, Suite 710 Pasadena, California 91101 (626)395-7801 Name: Sarah B. Adriano

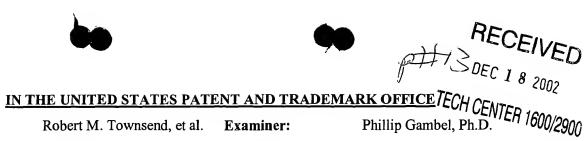
Reg. No.: 34,470
Initials: SBA

Customer No. 26,941









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BY BLOCKING LYMPHOCYTIC SIGNALS AND BY BLOCKING LFA-1

MEDIATED ADHESION

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b))

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

This Supplemental Information Disclosure Statement is being filed herewith as a supplement to Applicant's October 26, 2001, Information Disclosure Statement which was submitted under 37 C.F.R.§1.97 (b) before the mailing of a first Office Action on the merits.

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. They are as follows:

Battleman, David S., et al., 1993 J. Nurosci. "HSV-1 Vector-Mediated Gene Transfer of the Human Nerve Growth Factor Receptor P75hNGFR Defines High-Affinity NGF Binding," 13:941-951. (Exhibit 53)

Page 2

- Bolling, S.F., et al. 1996 J. Surg. Res. "The Time course of CTLAIg effect on cardiac allograft rejection," 63:320-323. (Exhibit 54)
- Bolling, S.F., et al., 1994 J.Surg.Res. "The Effect of combination cyclosporine and CTLA4Ig therapy on cardiac allograft survival," 57:60-64. (Exhibit 55)
- Dariavach, Piona., et al., 1988 Eur. J. Immunol. "Human Ig superfamily CTLA-4 gene: chromosomal localization and identity of protein sequence between murine and human CTLA-4 cytoplasmic domains," 18:1901-1905. (Exhibit 56)
- Fulmer, R.I., et al. 63 A.D. *The American Journal of Anatomy* "Transplantation of cardiac tissue into the mouse ear," 113:273-281. (Exhibit 57)
- Hansen, John A., et al., 1980 Immunogenetics "Monoclonal Antibodies Identifying a Novel
 T-Cell Antigen and Ia Antigen of Human Lymphocytes," 10:247-260. (Exhibit 58)
- Johnsson, B., et al., 1991 Anal. Biochem "Immobilization of Proteins to a
 Carboxymethyldextran-Modified Gold Surface for Biospecific Interaction Analysis in
 Surface Plasmon Resonance Sensors," 198:268-277. (Exhibit 59)
- Khilko, S.N., et al., 1993 J. Biol. Chem. "Direct Detection of Major Histocompatibility Complex Class I Binding to Antigenic Peptides Using Surface Plasmon Resonance," 268:15425-15434. (Exhibit 60)
- Lauzon, R.J., et al., 1989 *Cell Immunol*. "The Role of T cell receptors in non-MHC-restricted cytotoxicity," 118:265-284. (Exhibit 61)
- Carroll, R., et al., 1993 *Gene Therapy* "Construction and Characterization of Replication-Defective HIV-1 Packaging Cell", 17E:241: SZ401. (Exhibit 62)
- Linsley, Peter S., et al., 1992 *J.Ex.Med* "Coexpression and Functional Cooperation of CTLA-4 and CD28 on Activated T Lymphocytes," 176:1595-1604. (Exhibit 63)
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Page 3

- Linsley, Peter S., et al., 1995 *J. Biol. Chem.* "Binding Stoichiometry of the Cytotoxic T Lymphocyte-associated -Molecule-4 (CTLA-4)," 270:15417-15424. (Exhibit 65)
- Linsley, Peter S., and J.A. Ledbetter. 1993 Annu. Rev.Immol. "The Role of the CD28 receptor during T cell responses to antigen," 11:191-212. (Exhibit 66)
- Malik, Najma et al., 1989 Mol. and Cell. Biol. "Molecular Cloning, Sequence Analysis, and Functional Expression of a Novel Growth Regulator, Oncostatin M.,"
 9:2847-2853. (Exhibit 67)
- Martz, E., et al. 1985 Adv. Exp. Med. Biol. "Lymphocyte function-associated antigens: regulation of lymphocyte adhesions in vitro and immunity in vivo,"
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- Metzler, William J., et al., 1997 Nature Struct. Biol. "Solution structure of human CTLA-4 and delineation of a CD80/CD86 Binding Site Conserved in CD28,"
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- Price, M.R., et al., 1986 Br. J. Cancer "Epitope analysis of monoclonal antibody NCRC-11 defined antigen isolated from human ovarian and breast carcinomas,"
 54:393-400. (Exhibit 72)
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- Williams, Sander R., et al., 1991 *Proc. Natl. Acad. Sci.* "Introduction of foreign genes into tissues of living mice by DNA-coated microprojectiles," 88:2726-2730. (Exhibit 74)

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- Wingett, D., et al. 1999 *Cell Immunol*. "A Role for CD99 in T cell activation," 193:17-23. (Exhibit 75)
- Yokochi, Takashi, et al., 1982 Journal of Immunology "B Lymphoblast Antigen (BB-1)
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- Isobe, Mitsuaki., et al., 1997 *The Journal of Heart and Lung Transplantation* "Assessment of tolerance induction to cardiac allograft by anti-ICAM-1 and Anti-LFA-1 Monoclonal antibodies," 16:1149-1156. (Exhibit 78)
- Jaiswal, Archana I., et al., 1996 International Immunology "Regulation of CD40 ligand expression on naïve CD4 T cells: a role for TCR but not co-stimulatory signals,"
 8:275-285. (Exhibit 79)
- Suzuki, Jun-ichi, et al., 1997 The Journal of Heart and Lung Transplantation "Inhibition of accelerated coronary atherosclerosis with short-term blockade of intercellular adhesion molecule-1 and lymphocyte function-associated antigen-1 in a heterotopic murine model of heart transplantation," 16:1141-1148. (Exhibit 80)
- U.S. Patent No. 5,354,678 issued October 11, 1994 (Exhibit 81)
- U.S. Patent No. 5,824,655 issued October 20, 1998 (Exhibit 82)
- U.S. Patent No. 6,113,898 issued September 5, 2000(Exhibit 83)
- U.S. Patent No. 6,090,914 issued July 18, 2000 (Exhibit 84)
- International Publication No. WO 98/56417 published December 17,1998 (Exhibit 85)
- International Publication No. WO 95/34320 published December 21,1995 (Exhibit 86)
- Greene, J., et al., 1996 The Journal of Biological. Chem.. "Covalent Dimerization of CD28/CTLA-4 and Oligomerization of CD80/CD86 regulate T cell costimulatory interactions," 271:26762-26771. (Exhibit 87)

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This statement should be considered because it is submitted before the mailing date of the first

Office Action on the merits. In accordance with 37 C.F.R. §1.98(a) (2), copies of each document or

other information listed on the enclosed Form 1449 are provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and

103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that

the reference(s) are not "prior art." Moreover, Applicants do not represent that the references have

been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of

M.P.E.P. § 609, it is requested that the Examiner return a copy of the attached Form 1449, marked

as being considered and initialed by the Examiner, to the undersigned with the next official

communication.

No fee is deemed necessary in connection with the filing of this Supplemental Information

Disclosure Statement. However, if any additional fee is required, authorization is hereby given to

charge the amount of any such fee, or credit any overpayment, to Deposit Account No. 50-0306.

Respectfully submitted,

Sarah B. Adriano

Registration No. 34,470

Teresa Liang

Registration No. 51,946

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FORM 1449*

DISCLOSURE STATEMENT IN AN APPLICATION

Application Number **Docket Number** D0009NP;30436.53USU1 09/877,987 Applicant Robert M. Townsend et al. Filing Date Group Art Unit

1645

June 8, 2001

(Use several sheets if necessary)

		U.S. PAT	ENT DOCUMENT	rs				
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE December 21, 1992 February 15, 1995 June 7, 1995		
	5,354,678 (Exhibit 81)	October 11, 1994	Lebkowski et al					
	5,824,655 (Exhibit 82)	October 20, 1998	Border					
	6,113,898 (Exhibit 83)	September 5, 2000	Anderson et al.					
	6,090,914 (Exhibit 84)	July 18, 2000	Linsley et al.			April 15, 1994		
		FOREIGN P	ATENT DOCUME	NTS	<u> </u>			
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
						YES	NO	
	WO 98/56417 (Exhibit 85)	December 17, 19					X	
	WO 95/34320 (Exhibit 86)	December 21, 19					Х	
	OTHER I	OCUMENTS (Including	Author, Title, Da	ite, Pertinent Pag	es, Etc.)			
		n, David S., et al., 1993				er of the H	luman	
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		277. (Exhibit 59)						
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		R.J., et al., 1989 Cell Im		e of T cell recept	ors in non-MHC	-restricted		
		ity," 118:265-284. (Exh		an and Charact	imation of Doub	ation D.C	adina TITA	
		L., et al., 1993 <i>Gene The</i> ing Cell", 17E:241: SZ4		on and Character	ization of Keplic	anon-Defe	cuve HIV-	
	I Fackagi	mg Cen , 1/E.241. 324	OA. (EAHIDIL OZ)					

XAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

*Substitute Disclosure Statement Form (PTO-1449) Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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